Citation:

Caballero B, Clay T, Davis SM, Ethelbah B, Rock BH, Lohman T, Norman J, Story M, Stone EJ, Stephenson L, Stevens J; Pathways Study Research Group.Pathways: a school-based, randomized controlled trial for the prevention of obesity in American Indian schoolchildren. *Am J Clin Nutr*. 2003 Nov;78(5):1030-8.

PubMed ID: 14594792

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

The objective was to evaluate the effectiveness of a school-based, multicomponent intervention for reducing percentage body fat in American Indian school children..

Inclusion Criteria:

School selection was based on the following eligibility criteria:

1. projected 3rd grade enrollment of ≥ 15 children
2. 90% of 3rd grade children of American Indian ancestry
3. retention from 3rd to 5th grade over the past 3 years of ≥ 70%
4. school meals prepared and administered on site
5. availability of minimum facilities to deliver a physical activity program at the school
6. approval of the study by school, community and tribal authorities

Exclusion Criteria:

Schools that were considering closing or merging in the next 3 years were excluded.

Description of Study Protocol:

Recruitment

Elementary schools serving American Indian communities in Arizona, New Mexico, and South Dakota.

Design

The Pathways Study was organized in 2 phases. During the first 3 year phase, all components of the intervention were developed and tested, and measurement instruments were validated.

In the second phase, an intervention was implemented for 3 consecutive years.

Blinding used (if applicable)

To avoid operator bias, measurement teams were not involved in delivering the intervention. Training, certification and cross-validation of measurement staff were done centrally or regionally, supervised by the Measurement Committee.

Intervention (if applicable)

The intervention had four components:

1. change in dietary intake
2. increase in physical activity
3. classroom curriculum focused on healthy eating and lifestyle
4. a family involvement program

Statistical Analysis

Mixed linear models were used to test for intervention effects, with %BF at the end of 5th grade as the primary outcome variable. Fixed effects were baseline %BF and treatment group.

The SAS procedure PROC MIXED (SAS Institute, Cary, NC) was used to estimate all models.

The primary statistical analysis applied the intention-to-treat principle, which calls for all subjects to be analyzed according to thier treatment assignment at the time of randomization, regardless of whether they complete the study or not. Therefore, imputed values were used for missing data at follow-up (5th grade). For this, a prediction equation was developed with the use of data from control schools and procedure based on Rubin's multiple imputation method.

A secondary analysis was performed that included only students with both 2nd and 5th grade %BF measurements.

Data Collection Summary:

Timing of Measurements

Baseline (end of 2nd grade) and 3 years post intervention (end of 5th grade).

Dependent Variables

- Anthropometry: height and weight; triceps and subscapular skinfold thicknesses measured with Lange calipers; bioelectrical impedance with a single-frequency tetrapolar plethysmograph (Valhalla Scientific, Valhalla, NY)
- Physical Activity: measured with the use of both motion sensor and a self-reported activity questionnaire.
- Knowledge, attitudes, and behavior: measured with a questionnaire
- Dietary intake: measured during lunch by direct observation; food intake was calculated after all food left on the tray was measured. Twenty-four hour dietary recall was performed at the end of the study. Menu data were collected from 38 schools for breakfast and from 41 schools for lunch, representing menus offered during a 5-day period. All meal-composition

daa were analyzed with the use of the Nutrition Data System at the University of Minnesota.

Independent Variables

- Percentage body fat: estimated from bioelectrial impedance and anthropometry with the use of an equation developed and validated specifically for this study.

Control Variables

Description of Actual Data Sample:

Initial N: n=2058 assessed for eligibility

Attrition (final N): excluded: declined consent n=307; other reasons n=47

Randomly assigned: 1704

Allocated to intervention: n=879; lost to follow-up n=152; included in analysis n=727

Allocated to control: n=852, lost to follow up n=143; included in analysis n=682

Age: 3rd - 5th graders

Ethnicity: American Indian

Other relevant demographics: American Indian communities in Arizona, New Mexico and South Dakota

Anthropometrics

Baseline Measurements

	Intervention n=879	Control n=825
Percentage body fat	32.8	33.3
Height, cm	129.9	130.4
Weight, kg	32.5	32.9
BMI	19.0	19.1
triceps skinfold, mm	13.3	13.3
subscapular skinfold, mm	10.6	10.6

Summary of Results:

Key Findings

- The goal was not reached, and %body fat in both groups was essentially identical at the end of the intervention period.
- Total energy intake (by 24-hour dietary recall) was significantly reduced in the intervention schools but energy intake at school was not (percentage of energy from fat was observed at lunch in the intervention schools).
- Motion sensor data showed similar activity levels in both the intervention and control schools.
- Several components of knowledge, attitudes and behaviors were positively and signifcantly changed by the intervention.

Anthropometric measurements of American Indian children in the Pathways Study

	Baseline Intervention n=879	**Baseline Control n=825**	**Follow-up Intervention n=727**	**Follow-up Control n=682**	**Mean difference at follow-up**	**95% CI**	***P***
Percentage body fat	32.8	33.3	40.3	40.0	0.2	-0.84,1.31	0.664
Percentage body fat with imputation	-	-	39.8	39.8	0.0	-0.85,0.82	0.974
Height, cm	129.9	130.4	148.1	147.6	0.5	0.03,0.97	0.038
Weight, kg	32.5	32.9	49.0	49.0	-0.0	-0.86,0.86	0.996
BMI	19.0	19.1	22.0	22.2	-0.2	-0.50,0.15	0.298
triceps skinfold thickness, mm	13.3	13.3	17.2	17.2	0.1	-0.67,0.83	0.837
subscapular skinfold thickness, mm	10.6	10.6	15.0	15.0	-0.1	-0.85,0.70	0.848

Diet, physical activity, and knowledge, attitudes, and behaviors of American Indian children in the Pathways Study

	Mean at baseline Intervention	Mean at baseline Control	Mean at follow-up Intervention	Mean at follow-up Control	Mean difference at follow-up	95%CI	*P*
Dietary 24-hr recall n=621							
Energy (kcal)	-	-	1892	2157	-265	-437,-94	0.003
Fat (%of energy)	-	-	31.1	33.6	-2.5	-3.9,-1.1	0.001
School lunch observation n=683							
Energy (kcal)	522.9	573.6	500.2	494.4	5.8	-40.0,51.5	0.804
Fat (%of energy)	33.1	34.1	28.2	32.4	-4.2	-7.1,-1.3	0.005
Physical activity							
Motion sensor n=278(average vector magnitude/min	282.04	303.13	267.22	246.79	20.43	-19.05,59.92	0.310
Questionnaire n=1503	0.35	0.35	0.27	0.24	0.04	0.01,0.06	0.001
Knowledge							
3rd grade curriculum n=1150	0.46	0.46	0.77	0.65	0.11	0.08,0.15	0.001
4th grade curriculum n=1150	-	-	0.70	0.67	0.04	0.01,0.06	0.013
5th grade curriculum n=1150	-	-	0.55	0.48	0.07	0.03,0.11	0.001
Attitudes							
Physical activity self-efficacy n=1146	0.66	0.66	0.78	0.75	0.03	0.00,0.06	0.060

Food self-efficacy n=1149	0.69	0.72	0.75	0.76	-0.02	-0.05,0.02	0.332
Reported behaviors							
Food choice intentions n=1150	0.46	0.46	0.66	0.53	0.12	0.07,0.18	0.001

Author Conclusion:

These results document the feasibility of implementing a multicomponent program for obesity prevention in elementary schools serving American Indian communities. The program produced significant positive changes in fat intake and in food- and health-related knowledge and behaviors.

Reviewer Comments:

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes

2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes

5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes

	7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		N/A
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**		Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes